K091315

JUN - 5 2009

Section 5: 510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.98.

Date Prepared:	April 21, 2009
Sponsor	Covidien (formerly Confluent Surgical, Inc.) 101A First Avenue Waltham, MA 02451
Contact	Sean Reynolds Phone: (781) 839 1785 Fax: (781) 577 5808 E-mail: Sean.Reynolds@covidien.com
Device Trade/Proprietary Name	COVIDIEN Extended Tip Applicator
Classification Name	Piston Syringe (21 CFR 880.5860) Class II Product Code: FMF
Common Name	Extended Tip Applicator
Predicate Device(s)	Confluent Surgical Extended Tip Applicator - K072790
DEVICE DESCRIPTION	
Product Description	The COVIDIEN Extended Tip Applicator is a single-use, disposable applicator intended for the simultaneous delivery of two non-homogenous solutions onto a surgical site. The COVIDIEN Extended Tip Applicator provides two (2) female luer fittings for connection to standard syringes containing two non-homogenous solutions. The shaft of the Extended Tip Applicator maintains two separate and independent lumens, which keep the two solutions separate and prevent premature mixing. The Extended Tip Applicator shaft is bendable up to 60 degrees to facilitate access to confined spaces at the surgical site.
Indications for Use	The COVIDIEN Extended Tip Applicator is indicated for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.
Safety and Effectiveness	Safety and effectiveness of the Extended Tip Applicator have been demonstrated in this submission. Biocompatibility testing assures the device complies with applicable sections of industry and safety standards. Performance testing ensures that the Extended Tip Applicator meets all of its functional requirements and performs as intended.
Conclusion	Performance data, identical indications for use and identical operating principle demonstrate the Covidien Extended Tip Applicator to be substantially equivalent to a predicate device under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Sean Reynolds
Senior Associate, Regulatory Affairs
Confluent Surgical, Incorporated
101A First Avenue
Waltham, Massachusetts 02451

JUN - 5 2009

Re: K091315
Trade/Device Name: Covidien Extended Tip Applicator
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: May 1, 2009
Received: May 4, 2009

Dear Mr. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091315

Indications for Use Statement

510(k) Number (if known): K091315

Device Name: Extended Tip Applicator

Indications for Use: The Extended Tip Applicator is indicated for use in the simultaneous delivery of two non-homogenous solutions onto a surgical site.

Prescription Use __X__ AND/OR Over-the -Counter Use

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for LCDR. Colburn

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K091315